

Food and Drug Administration, HHS

§ 870.3300

(b) *Classification*. Class II (performance standards).

§ 870.2880 Ultrasonic transducer.

(a) *Identification*. An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

(b) *Classification*. Class II (performance standards).

§ 870.2890 Vessel occlusion transducer.

(a) *Identification*. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) *Classification*. Class II (performance standards).

§ 870.2900 Patient transducer and electrode cable (including connector).

(a) *Identification*. A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

(b) *Classification*. Class II (performance standards).

§ 870.2910 Radiofrequency physiological signal transmitter and receiver.

(a) *Identification*. A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

(b) *Classification*. Class II (performance standards).

§ 870.2920 Telephone electrocardiograph transmitter and receiver.

(a) *Identification*. A telephone electrocardiograph transmitter and receiver is a device used to condition an electrocardiograph signal so that it can be transmitted via a telephone line to an-

other location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

(b) *Classification*. Class II (performance standards).

Subpart D—Cardiovascular Prosthetic Devices

§ 870.3250 Vascular clip.

(a) *Identification*. A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels other than intracranial vessels.

(b) *Classification*. Class II (performance standards).

§ 870.3260 Vena cava clip.

(a) *Identification*. A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

(b) *Classification*. Class II (performance standards).

§ 870.3300 Vascular embolization device.

(a) *Identification*. A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see § 882.5950 of this chapter.

(b) *Classification*. Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices." For availability of this guidance document, see § 870.1(e).

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